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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,939	02/19/2002	Leon W.M.M. Terstappen	Immu.Rapid	6526

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,939	TERSTAPPEN ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/17/2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon review of the new amendment filed on 17 February 2205, and reconsideration, the earlier Restriction Requirement is vacated and replaced with the following new Restriction.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I.. Claims 1-19, 24-28, drawn to method of assessing malignancy by obtaining biological sample using EpCAM antibody, and using at least one ligand capable of binding cancer marker listed in Table XII (total 48 different markers counted by the examiner) expressed on an epithelial cancer cells, then followed by various art-known technique to count the bound cells, classified in class 435, subclass 6, and 7.23.

Group II. Claims 29-54, drawn to method of assessing non-hematopoietic malignancy by obtaining biological sample using EpCAM antibody, and using at least one ligand capable of binding cancer marker listed in Table XII (total 48 different markers counted by the examiner) expressed on an epithelial cancer cells, then followed by various art-known technique to count the bound cells, classified in class 435, subclass 6, and 7.23.

Group III. Claims 20, 21, and 23, drawn to a malignant cell, and a tumor vaccine classified in class 435, subclass 320.1.

Group IV. Claim 22, drawn to an altered diathesis associated molecule, classified in class 530, subclass 350.

Group V. Claims 55-72, drawn to method of determining alterations in tumor diathesis associated molecules listed in 67, 68 (total 59 counted), classified in class 435, subclass 7.23.

Group VI. Claims 73-75, drawn to method of whole body biopsy using each of the molecules listed in claim 74 (total 59 different molecules counted), classified in class 435, subclass 7.23.

Group VII. Claim 76, drawn to method for identifying alterations in a circulating tumor cells using associated molecule, classified in class 435, subclass 7.1.

Group VIII. Claims 77-83, drawn to kit comprising at least one binding agent for each of the cancer markers listed in claim 79 (total 59 counted), classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

The group VIII and the method groups I, II, V, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit as claimed can be used in a materially different process of groups I, II, V, VI .

The group IV and the method group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit as claimed can be used in a materially different process of making an antibody.

Inventions groups I, II, and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different method requiring different effects, and/or requiring different reagents.

Inventions groups III, IV, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different products with different operations and different functions.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I contains claims drawn to two genuses of the following patentably distinct species:

First genus is the molecule listed in Table XII are different molecules with different structures and biological functions.

Second genus is the different detection methods listed in claims 5, 16, and 25-28.

If group I is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species or claimed species from each of the two genuses for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable

Group II contains claims drawn to four genuses of the following patentably distinct species:

First genus is the molecule listed in Table XII are different molecules with different structures and biological functions.

Second genus is the different detection methods listed in claims 30, and 33.

Third genus is the different cancers listed in claims 34, 40-45, 51-54.

Fourth genus is the different tumor diathesis-associated molecules listed in claims 35-39, 46-50.

If group II is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species or claimed species from each of the four genuses for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Group V contains claims drawn to following patentably distinct species:

The different tumor diathesis associated molecule in claims 67, and 68 are different molecules with different structures and biological functions.

If group V is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Group VI contains claims drawn to two genuses of the following patentably distinct species:

First genus is the different tumor diathesis associated molecule in claim 74, which are different molecules with different structures and biological functions.

Second genus is the different cancers in claims 75.

If group VI is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species or claimed species from each of the two genuses for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Group VIII contains claims drawn to following patentably distinct species:

The different tumor diathesis associated molecule in claims 79-82 are different molecules with different structures and biological functions.

If group VIII is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations

of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

5/16/05